

REMARKS

Claims 1-10, 15, 16 and 18-24 are pending in the current application. Claims 11-14 and 17 were canceled previously. Claims 1-8, 15 and 16 are amended herein. Claims 18-24 have been added.

Applicant respectfully request reconsideration of the application in view of the foregoing amendments and the remarks appearing below.

Request for Examiner Interview

Applicant respectfully requests a telephonic Examiner Interview between the Examiner and the below-signed attorney, Morgan Heller II. Mr. Heller II will contact the Examiner to set up the Interview in due time. The U.S. Patent and Trademark Office (USPTO) is respectfully requested to refrain from deciding whether or not to reject the presently amended claims until after the Interview so that the Examiner can consider the issues discussed in the Interview.

Comments on the USPTO's Responses to Applicant's Prior Arguments

On pages 5-7 of the current Office Action, the USPTO presents responses to Applicant's arguments filed on February 26, 2008. Applicant wishes to take an opportunity, prior to addressing the claim rejections in detail, to respond to some of those responses.

Regarding the response in item 9 of the current Office Action, the USPTO states that "In the instant case, Sternby discloses that the whole body clearance ratio, K, may be calculated from the disclosed variables, and does not disclose that those variable are unattainable." [Emphasis added.] This statement demonstrates to Applicant that the USPTO is (improperly) blurring the distinction between "whole body clearance" (which in the Sternby publication is denoted "K") and a "whole body clearance ratio," which the current application, including the claims, clearly define as a ratio of two clearances, namely, a whole body clearance to a potential clearance capacity of a dialyzer. When the USPTO recognizes there is a significant distinction between the two terms, Applicant is confident the USPTO will realize the error in the present rejections.

Regarding the response in item 8 of the current Office Action, the USPTO states that “Applicant’s claim language merely relates whole body clearance to the cleaning capacity without actually using the values of the cleaning capacity to generate the clearance ratio. Accordingly, Sternby suggests the calculation of the clearance ratio as claimed by Applicant.”

Applicant believes the above-quoted statement of the USPTO is driven by the misapprehension by the USPTO of the difference between a “clearance” and a “clearance ratio” as mentioned above and discussed below in detail. Applicant respectfully submits that, while the Sternby publication mentions various clearances, i.e., whole body clearance and effective clearance, the Sternby publication is completely silent on determining a clearance ratio. Therefore, the assertion in item 8 of the current Office Action is not correct even with respect to the claims as they stood prior to the current amendments. The originally filed claims required determination of a clearance ratio, and the Sternby publication clearly does not disclose such a ratio of clearances.

In addition, the statement that “Applicant’s claim language merely relates whole body clearance to the cleaning capacity without actually using the values of the cleaning capacity to generate the clearance ratio” appears to misperceive the present invention. In some embodiments of the present invention, including explicitly claimed embodiments, Applicant has disclosed ways to determine whole body clearance ratios (i.e., K_{wb}/K and K_{wb}/K_{eff}) without directly using values for the potential clearance capacities K and K_{eff} . Rather, the ratios themselves (as opposed to the individual clearances that constitute the ratio) can be estimated without actually determining values of the clearances K_{wb} , K and K_{eff} . See, e.g., the right hand sides of the equations in paragraphs [0040] and [0057] (these paragraph identifiers appear in the publication of the current application) that show ways of calculating whole body clearance ratios without directly calculating the constituent clearances. These ways are useful because they avoid otherwise difficult or impractical calculations. Herein lies an important benefit of Applicant’s invention. So, in fact, ones of the current claims do not actually use values of K and K_{eff} to calculate the ratios as the USPTO appears to be suggesting is required to define over the Sternby publication.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 6 and 16 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the USPTO states that the language added in a prior response to the effect that the whole body clearance ratio is a dimensionless positive numeral smaller than one is unsupported by the specification as originally filed.

Applicant has removed the referenced language. Therefore, the present rejection is moot, and Applicant respectfully requests withdrawal of the present rejection.

While the present rejection is now moot, Applicant respectfully submits that the phrase in question (now deleted) would indeed satisfy the written description requirement. In particular, when the claim term “whole body clearance ratio” is given its proper meaning in light of the specification, i.e., that “whole body clearance ratio” means a ratio of a whole body clearance to a potential clearance capacity of a dialyzer, it is clear to those having ordinary skill in the art that the result is dimensionless. A clearance divided by a clearance, i.e., $K1/K2$, has no dimensions because the dimensions of $K1$ in the numerator and the like dimensions of $K2$ in the denominator cancel one another. Further, since it is well-known that a body clearance, such as a whole body clearance, will, in actual practice, always be less than the potential clearance capacity of the dialyzer because of the practical limits of dialysis in achieving an actual body clearance equal to the theoretical clearance potential of the dialyzer (which would result in a ratio of 1), those of ordinary skill in the art will instantly recognize that the ratio of the body clearance to potential clearance capacity will always be less than 1.

The USPTO is reminded that there is no *in haec verba* requirement for a newly added claim limitation to meet the written description requirement of 35 U.S.C. § 112. See, e.g., MPEP § 2163.I.B. Rather, the newly added limitation can meet the written description requirement if it is implicitly or inherently disclosed in the original specification. *Id.* In the present case, Applicant respectfully submits that anyone having ordinary skill in the art and properly understanding “whole body clearance ratio” to be a ratio of whole body clearance to potential clearance capacity, will readily understand that the original version of the current application

implicitly discloses that the whole body clearance ratio will be both less than one and a dimensionless value. Therefore, Applicant respectfully submits that the present rejection would have been improper had the phrase at issue remained in the claims.

Rejection Under 35 U.S.C. § 103

Sternby

Claims 1-10, 12 and 14-16 stand rejected under 35 U.S.C § 103(a) as being obvious in view of International Application Publication No. 98/55166 to Sternby (hereinafter, “the Sternby Publication”). Applicant respectfully disagrees.

In the cited publication, Sternby discloses a method and apparatus for calculating the mass of a composition in a fluid volume and for calculating efficiency of exchange of the composition with an exchange fluid. Importantly, and as discussed further below, the Sternby publication does not disclose or suggest the determining of values of whole body clearance ratios as claimed in the amended claims and, indeed, as claimed in the original claims.

In this connection, Applicant desires to point out that the calculated measures in the Sternby publication (i.e., K/V and K_d/V) are completely different from, and are not equivalent to, the calculated measures in the current application (i.e., K_{wb}/K_{eff} and K_{wb}/K). The measures K/V and K_d/V of the Sternby publication relate treatment efficiency to the size of the patient, whereas the inventive measures K_{wb}/K_{eff} and K_{wb}/K of the current application relate treatment efficiency to a theoretical maximum efficiency. A useful distinction between the two differing sets of measures is that the measures of the Sternby reference can be increased simply by prolonging a treatment session, whereas the measures of the present invention cannot be increased by prolonging a treatment session. An important use of the treatment-length independence aspect of the measures of the present invention in the context of dialysis is that these measures can be used in determining adjustments to dialysis parameters other than session length. Such a benefit eluded skilled artisans prior to the present invention.

In the present rejection, the USPTO makes several assertions that are not accurate and that lead Applicant to believe the rejection is misguided.

First, and as touched on above, the USPTO asserts that the Sternby publication discloses the concept of a whole body clearance ratio. This is not true. The Sternby publication discloses the concept of whole body clearance, which, as well-known in the art, is defined as the ratio removal rate to equilibrated concentration in the subject's body. Whole body clearance is typically denoted by " K ," " K_{wb} " or other similar identifier. See, e.g., the background section of the current application and page 10, lines 18-20 of the Sternby publication for support for the meaning of "clearance." In other words, by definition, whole body clearance is a ratio. Thus, to say "whole body clearance ratio" when referring to a whole body clearance (K_{wb}) is improper because the whole body clearance is a ratio. That is, the word "ratio" in the term "whole body clearance ratio" is redundant because the term "ratio" is inherently part of the definition of whole body clearance. This is akin to saying "the ratio ratio," which is nonsensical. Thus, the term "whole body clearance ratio" must mean something other than just "whole body clearance." In fact, it does, and this meaning is clearly provided by the current specification as originally filed.

In particular and as provided by the current specification, a whole body clearance ratio is a ratio of whole body clearance (here, denoted K_{wb}) to a clearance capacity of a dialyzer (here, either K or K_{eff}). Clearly, the Sternby publication does not disclose or suggest determining a ratio of two clearances, let alone the particular ways to calculate the ratio that appear in various ones of the rejected claims.

Second, the USPTO asserts on page 3 of the current Office Action that the method disclosed in the Sternby publication "is capable of generating a clearance ratio within the values set forth by applicant." Applicant believes the USPTO is asserting that the whole body clearance or effective clearance, or both, disclosed in the Sternby publication could have values less than one and are dimensionless. This simply is not so because clearances (again, which the USPTO is improperly calling "clearance ratios") are not dimensionless. Because clearances are defined as removal rate (e.g., mass/time) divided by concentration (e.g., mass/volume), their dimensions are volume/time. In contrast, it is clearly seen that the whole body clearance "ratios" of the present claims, which are defined as a first type of clearance (volume/time) divided by a second type of clearance (also, volume/time) are truly dimensionless.

Turning now to the claims in detail, amended independent claim 1 now requires “determining a whole body clearance ratio (K_{wb}/K_{eff} , K_{wb}/K) value representing a whole body clearance of the patient divided by the potential clearance capacity (K_{eff} , K) of the dialyzer.” [Emphasis added.] Consequently, amended claim 1 (and its dependent claims) now explicitly define the whole body clearance ratio as whole body clearance divided by potential clearance capacity of the dialyzer. In this connection, Applicant notes that in item 8 on page 6 of the current Office Action the USPTO states that “the Applicant does not actually claim the steps of determining the whole body clearance ratio based on or using the values of the potential cleaning capacity.” [Emphasis in original.] Applicant respectfully submits that the current amendment to claim 1 rectifies any perceived issue in this regard. (That said, Applicant believes that the fact that the term “whole body clearance ratio” is effectively defined in the present application as being a ratio of clearances obviates the need for the present amendment.)

Regarding the change from “cleaning capacity” to “clearance capacity,” those skilled in the art will readily understand that “cleaning” and “clearance” in the present context are synonymous. Applicant has made the change to further emphasize that the resulting ratio is indeed a dimensionless value as discussed above. It is Applicant’s position that the above-quoted step of amended claim 1 is clearly not disclosed or suggested by the Sternby publication.

Because the Sternby publication does not disclose or suggest the above-quoted step of amended claim 1 and no other reference of record discloses or suggests that step, amended claim 1 cannot be obvious in view of the Sternby publication, nor can claims 2-5 that depend therefrom.

Regarding independent claim 6, this claim has been amended to similarly require the step of “determining the whole body clearance ratio (K_{wb}/K_{eff}) value so as to represent a whole body clearance divided by an effective clearance of the dialysis treatment.” [Emphasis added.] Consequently, the present rejection is improper for amended claim 6 (and its dependent claims 7-10) in the same manner it is improper for claim 1.

Regarding claim 15, this claim relies on either one of amended independent claims 1 and 6. Therefore, it, too, is patentable over the Sternby publication for at least the reasons discussed above relative to amended claims 1 and 6.

Regarding independent claim 16, this claim as amended requires, among other things, “a processor configured to determine a whole body clearance ratio (K_{wb}/K_{eff}) value for the patient, said whole body clearance ratio (K_{wb}/K_{eff}) representing a whole body clearance of the patient divided by an effective clearance.” [Emphasis added.] Applicant respectfully submits that this limitation explicitly defines the whole body clearance ratio to include the effective clearance in the denominator so as to require the ratio to be a dimensionless number. Consequently, amended claim 16 is patentable over the Sternby publication for at least the same reasons discussed above relative to amended claim 1.

In addition to all of the pending claims being patentable over the Sternby publication for the reasons just discussed, Applicant respectfully submits that the various specific processes for directly calculating whole body clearance ratios, i.e., K_{wb}/K and K_{wb}/K_{eff} (again, as distinguished from a clearance itself (e.g., K)), appearing in many of the claims, such as in claims 2-10, 15 and 16, are separately patentable relative to the patentability discussed above. This is so at least because even though the Sternby publication may disclose such generic tasks as measuring urea concentrations, taking blood samples, using slope of a concentration curve to find an initial urea mass, none of these tasks are used in determining a whole body clearance ratio. Therefore, these claims cannot be rendered obvious by the Sternby publication.

For at least the foregoing reasons, Applicant respectfully requests withdrawal of the present rejection.

Patentability of New Claims 18-24

New claims 18-24 are “Beauregard claims” directed to computer-readable media containing computer executable instructions that perform various steps of method claims 1, 2 and 5-8. Applicant respectfully submits that new claims 18-24 are patentable over the references

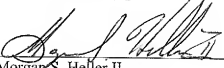
of record for the same reasons that claims 1, 2 and 5-8 are patentable over the references of record.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that claims 1-10, 15, 16 and 18-24, as amended and newly added, are in condition for allowance. If any issues remain, the Examiner is encouraged to call the undersigned attorney at the number listed below.

Respectfully submitted,

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